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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,867	08/18/2006	Martha Li	D0310 NP	2857

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
07/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,867	LI ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-10 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, drawn to a method for testing or predicting whether a mammal will respond therapeutically to a method of treating cancer comprising administering an agent that modulates cdk activity, wherein the method comprises: (a) measuring in the mammal the level of the nucleotide sequence of SEQ ID NO: 1246; (b) exposing the mammal to the agent that modulates cdk activity; and (c) following the exposing of step (b), measuring in the mammal the level of the nucleotide sequence of SEQ ID NO: 1246, wherein a difference in the level of the nucleotide sequence of SEQ ID NO: 1246 measured in step (c) compared to the level of the nucleotide sequence of SEQ ID No: 1246 measured in step (a) indicates that the mammal will respond therapeutically to said method of treating cancer.

Group II, claims 3-4, drawn to a method for determining whether a mammal is responding to an agent that modulates cdk activity, comprising: (a) obtaining a biological sample from the mammal; (b) measuring in said biological sample the level of the nucleotide sequence of SEQ ID NO:1246; (c) correlating said level of the nucleotide sequence of SEQ NO:1246 with a baseline level; and (d) determining whether the mammal is responding to an agent that modulates cdk activity based on

said correlation.

Group III, claims 5-8, drawn to a method for testing or predicting whether a mammal will respond therapeutically to a method of treating cancer comprising administering an agent that modulates cdk activity, wherein the method comprises: (a) measuring in the mammal the level of at least one biomarker selected from the biomarkers of Table 1; (b) exposing the mammal to the agent that modulates cdk activity; (c) following the exposing of step (b), measuring in the mammal the level of the at least one biomarker, wherein a difference in the level of the at least one biomarker measured in step (c) compared to the level of the at least one biomarker measured in step (a) indicates that the mammal will respond therapeutically to said method of treating cancer.

Group IV, claim 9, drawn to a method for determining whether a mammal is responding to an agent that modulates cdk activity, comprising: (a) obtaining a biological sample from the mammal; (b) measuring in said biological sample the level of at least one biomarker selected from the biomarkers of Table I; (c) correlating said level of at least one biomarker with a baseline level; and (d) determining whether the mammal is responding to an agent that modulates cdk activity based on said correlation.

Group V, claim 10, drawn to a method for determining whether a mammal is responding to an agent that modulates cdk activity, comprising: (a) exposing the mammal to the agent; and (b) following the exposing of step (a), measuring in the mammal the level of at least one biomarker selected from the biomarkers of Table 1, wherein a difference in the level of the at least one biomarker measured in step (b), compared to the level of the at least one biomarker in a mammal that has not been exposed to said agent, indicates that the mammal is responding to the agent that modulates cdk activity.

3. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. In this case, the inventions are not linked by a special technical feature because the different methods of Groups I-V are practiced on different populations of mammals, e.g., mammals that have not been exposed to an agent that modulates cdk activity or mammals that are being treated with an agent that modulates cdk activity, and/or the methods measure the levels of structurally different biomarkers from structurally different samples. Furthermore, PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept to comprise more than the first mentioned product, the first mentioned method for making said product, and the first mentioned method for using said product.

For these reasons, the special technical feature of the invention of Group I is predicting whether a mammal will respond therapeutically to a method of treating cancer comprising administering an agent that modulates cdk activity by: (a) measuring in the mammal the level of the nucleotide sequence of SEQ ID NO: 1246; (b) exposing the mammal to the agent that modulates cdk activity; and (c) following the exposing of step (b), measuring in the mammal the level of the nucleotide sequence of SEQ ID NO:1246.

The special technical feature of the invention of Group II is determining whether a mammal is responding to an agent that modulates cdk activity by: (a) obtaining a biological sample from the mammal; (b) measuring in said biological sample the level of the nucleotide sequence of SEQ ID NO:1246; (c) correlating said level of the nucleotide sequence of SEQ NO:1246 with a baseline level; and (d) determining whether the mammal is responding to an agent that modulates cdk activity based on said correlation.

The special technical feature of the invention of Group III is predicting whether a mammal will respond therapeutically to a method of treating cancer comprising administering an agent that modulates cdk activity by: (a) measuring in the mammal the level of at least one biomarker selected from the biomarkers of Table 1; (b) exposing the mammal to the agent that modulates cdk activity; (c) following the exposing of step (b), measuring in the mammal the level of the at least one biomarker.

The special technical feature of the invention of Group IV is determining whether a mammal is responding to an agent that modulates cdk activity by: (a) obtaining a biological sample from the mammal; (b) measuring in said biological sample the level of at least one biomarker selected from the biomarkers of Table I; (c) correlating said level of at least one biomarker with a baseline level; and (d) determining whether the mammal is responding to an agent that modulates cdk activity based on said correlation.

The special technical feature of the invention of Group V is determining whether a mammal is responding to an agent that modulates cdk activity by: (a) exposing the mammal to the agent; and (b) following the exposing of step (a), measuring in the mammal the level of at least one biomarker selected from the biomarkers of Table 1.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

4. This application contains claims directed to more than one species of the generic inventions of Groups III-V. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of the processes of Groups III-V are as follows:

Measuring the level of one biomarker selected from the biomarkers of Table 1.

5. Accordingly, if Applicant elects any of Groups III-V, Applicant is required, in reply to this action, to elect a single species of biomarker presented in Table 1 (Table 1 starts of page 13 of the specification) to which the claims shall be restricted if no generic claim

is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Notably, PCT Rule 13.2 sets forth that alternatives claimed in the same claim are linked by a special technical feature when the alternatives are of a similar nature. PCT Rule 13.2 further sets forth that alternatives are of a similar nature when:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In this case, while the species of biomarker listed in Table 1 are asserted to all have the common property of being biomarkers for predicting whether a mammal will respond to an agent that modulates cdk activity, each biomarker represents a structurally distinct polynucleotide and/or polypeptide that comprises different nucleotide sequences and/or amino acid sequences, respectively. Accordingly, the species of biomarkers listed in Table 1 are not of a similar nature because they all do not share a significant structural element and because they all do not belong to the same

recognized class of chemical compound in the art.

For these reasons, measuring the levels of each of these different species of biomarker in any of these different inventions is not deemed to share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

7. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined and, if necessary,** a species of invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.** The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
July 10, 2008